



Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates)
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	3M Company	
Manufacturer address and contact details	2510 Conway Avenue, Saint Paul, MN 55144 USA	
Single Registration Number (SRN) (if available)	US-MF-000014086	
Authorised Representative name (if applicable)	3M Deutschland GmbH	
Authorised Representative address and contact details	Carl-Schurz-Str. 1, 41453 Neuss Germany	
Single Registration Number (SRN) (if available)	DE-AR-000011643	
Notified body name (if applicable)	BSI Group The Netherlands B.V.	√ See attached schedule
Notified body number (if applicable)	2797	√ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	CE 00493 CE 02242 CE 525600 CE 698003 CE 89073	√ See attached schedules
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	May 26, 2024 April 27, 2024	√ See attached schedule
End date of extended validity/transition period	December 31, 2028 December 31, 2027	√ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*¹
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service, namely by fulfilling the following conditions:

O Directive Certificate(s) as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Choose applicable statements:

- Expired *before* 20 March 2023:
- Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
- A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
- A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intend to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

Expired/expires *after* 20 March 2023:

¹ The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body



Choose one applicable statement:

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

○ Quality Management System (QMS)

Choose one applicable statement:

- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- A QMS in accordance with Article 10(9) MDR is in place.
- A notified body has issued the attached certificate for the MDR-compliant QMS.

○ Device(s) as listed in the attached schedule

- The device(s) continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

3M Company, 2510 Conway Avenue, Saint Paul MN 55144 USA

Nadia Battah

Nadia Battah
Regulatory Affairs Manager
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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period	Substitute Device(s) (if applicable)
3M™ Cavilon™ Advanced Skin Protectant	CE 00493	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2028	N/A
3M™ Curoso™ Disinfecting Caps, Tips, and Cap Strips	CE 00493	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2028	N/A
3M™ Cavilon™ No Sting Barrier Film (Wipes/wands)	CE 00493	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2028	N/A
3M™ Bair Hugger™ Warming Blankets (Sterile)	CE 00493	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2028	N/A
3M™ Coban™ Self-Adherent Wrap (Sterile)	CE 00493	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2028	N/A
3M™ Steri-Strip™ Closures	CE 00493	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2028	N/A
3M™ Medipore™ +Pad Cloth Adhesive Wound Dressing	CE 00493	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2028	N/A
3M™ Steri-Drape™ Isolation Bag and Wound Edge Protector Drape	CE 00493	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2028	N/A



Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period	Substitute Device(s) (if applicable)
3M™ Steri-Drape™ Surgical Drape and Accessories	CE 00493	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2028	N/A
3M™ Skin Stapler Remover	CE 00493	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2028	N/A
3M™ Tegaderm™ CHG I.V. Securement Dressing	CE 02242 CE 525600	May 26, 2024 April 27, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2027	N/A
3M™ Tegaderm™ CHG I.V. Port Dressing	CE 02242 CE 525600	May 26, 2024 April 27, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2027	N/A
3M™ Tegaderm™ Antimicrobial Transparent Dressing	CE 02242 CE 698003	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2027	N/A
3M™ Tegaderm™ Antimicrobial I.V.	CE 02242 CE 698003	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2027	N/A
3M™ Ioban™ 2 Antimicrobial Incise Drapes	CE 02242 CE 89073	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2027	N/A
3M™ Steri-Drape™ Ioban™ 2 Specialty Drapes	CE 02242 CE 89073	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2027	N/A
3M™ Electrosurgical Plates	CE 02242	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2028	N/A
3M™ Steri-Vac™ Sterilizers /Aerators and Steri-Gas™ cartridges	CE 02242	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2028	N/A



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3M™ Ranger™ Pressure Infusor	CE 02242	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2028	N/A
3M™ Ranger™ Blood/Fluid Warming Unit	CE 02242	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2028	N/A
3M™ Bair Hugger™ Warming Unit and Sensor	CE 02242	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2028	N/A
3M™ Bair Hugger™ Temperature Monitoring System, Sensor and Control Unit	CE 02242	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2028	N/A
3M™ Ranger™ Blood/Fluid Warming Disposable Sets	CE 02242	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2028	N/A
3M™ Ranger™ Irrigation Fluid Warming Unit	CE 02242	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2028	N/A
3M™ Ranger™ Irrigation Fluid Warming System Disposable Sets	CE 02242	May 26, 2024	BSI Group The Netherlands B.V., BSI 2797	BSI Group The Netherlands B.V., BSI 2797	December 31, 2028	N/A